IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA	)	
	)	
	)	
v.	)	**Case No. 2:19-cr-00003-1**
	)	**Judge Aleta A. Trauger**
	)	
HEATHER MARKS	)	

MEMORANDUM and ORDER

Before the court is the government's Motion to Exclude the Expert Testimony of Michael W. Staples. (Doc. No. 308.) For the reasons set forth herein, the motion will be granted in part and denied in part.

I. BACKGROUND

Defendant Marks, a nurse practitioner, is charged in a Superseding Indictment with distributing and conspiring (with her former co-defendant, Hemal Mehta, M.D.) to distribute Schedule II controlled substances outside the usual course of professional practice and without a legitimate medical purpose. She intends to proffer at trial the expert testimony of James Patrick Murphy, MD, and James Darren McCoy, FNP-BC, CPE.[1] (Doc. Nos. 271-1, 274.) Dr. Murphy intends to offer his opinion that the "prescriptions for controlled substances issued by NP Marks, as noted in the Superseding Indictment . . . , were issued for a legitimate medical purpose and in the usual course of professional practice" and, moreover, that the "'usual course of professional practice' is simply not the same as the 'standard of care'" that would be applicable, for instance,

[1] These initials indicate that he is a Board Certified Family Nurse Practitioner and Certified Pain Educator. (*See* Doc. No. 274 at 3.)

in a medical malpractice case. (Doc. No. 271-1 at 1, 23.) Similarly, Mr. McCoy intends to testify generally that, while Marks "does not appear to have been skilled at recognizing aberrant behaviors," the medical records of the patients at issue indicate that she prescribed "opiate analgesics . . . in the usual course of [her] professional practice and for legitimate medical purpose." (Doc. No. 274 at 23, 22.) The government does not seek to exclude either of these witnesses from testifying.

The defendant also seeks to introduce the testimony of Michael W. Staples, CMBI,[2] as a "Regulatory and Legal Health Care Compliance Expert." (*See* Doc. No. 287-2 at 1.) Marks has submitted an Expert Report and Opinion ("Report") by Staples, showing that he proposes to testify about (1) the challenges of "Rural Healthcare"; (2) the characteristics of a "Pill Mill" and "bad faith-controlled substance prescribing"; and (3) patient stigma related to controlled substance prescribing and addressing aberrant issues. (Report, Doc. No. 287-1 at 7.)

Under the first heading, Staples states that he has "frequently investigated and worked with primary healthcare practitioners in rural settings," and he opines that the factors that distinguish the rural setting—limited resources, impoverished patient population, etc.—may cause prescribing providers in the rural setting to "make medical decisions that may seem out of the standard of care for a prescribing provider from a larger city but is within the standard of care for that rural community." (*Id.*)

Second, he states that, based on his experience, "prescribing providers who prescribe controlled substances [in] 'bad faith' do so for one of three reasons": (1) money; (2) sex or sexual favors; or (3) the prescriber's own addiction to controlled substances. (*Id.* at 8.) He opines that operating a so-called "pill mill" is an example of bad faith prescribing and that Marks' practice

[2] CMBI stands for Certified Medical Board Investigator. (Doc. No. 287-2 at 4.)

did not show characteristics consistent with the operation of a pill mill, which he enumerates as including such hallmarks as (1) accepting cash payments only; (2) conducting little or no physical exam of the patient; (3) prescribing the type and amount of the medication the plaintiff wants; (4) directing patients to a specific pharmacy; (5) treating pain complaints with controlled substances only and ignoring patients' other medical conditions; and (6) prescribing drug "cocktails," among others. (*Id.*)

Third, Staples seeks to testify about "patient stigma relating to chronic pain and controlled substance prescribing." (*Id.* at 9.) He quotes at length from a report issued by the U.S. Department of Health and Human Services ("HHS"), titled "Pain Management Best Practices Final Report," which refers to a "growing body of empirical research into stigmatization and the resulting barriers to care" and emphasizes that "[c]ompassionate, empathetic care in a provider-patient partnership is best for countering the stigma, isolation, and psychosocial challenges of living with pain." (*Id.*) He also reproduces a "visual" created by the U.S. Centers for Disease Control and Prevention ("CDC"), titled "The Chronic Pain Experience: Understand access to covered treatment and services for people with chronic pain." (*Id.* at 11.) He concludes from these documents that "patients can have a substance use disorder that is not connected directly to their chronic pain condition and still requires treatment, or the patient may take medical care into their own hands," which may lead to overdose or even death from self-medicating with illegal drugs. (*Id.*)

Finally, although not listed in his summary of topics, Staples opines that, while urine drug testing in patients with chronic pain is a "valuable 'tool,'" it should "never override an educated healthcare practitioner's medical judgement and decision making" and "should never be the sole

basis for diagnosis and treatment decision making." (*Id.* at 11–12.) He cites a SAMSHA report[3] that lists many reasons why a drug test may unexpectedly be negative. (*Id.* at 12.)

Citing Federal Rule of evidence 702 as well as Rules 401 and 403, the government's Motion to Exclude argues that Staples is not qualified to testify as an expert to offer the evidence he proposes to offer and that his proposed testimony is both unreliable and irrelevant.

II. STANDARD OF REVIEW

Federal Rule of Evidence 702 governs the admissibility of expert testimony. A party offering an expert's opinion bears the burden of establishing the admissibility of such opinion by a preponderance of the evidence. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 344, 251 (6th Cir. 2001). Expert testimony is admissible only if it satisfies the requirements of Rule 702, which states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods, and;
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Thus, under Rule 702, the court must, as a threshold matter, determine whether a proffered expert is qualified "by knowledge, skill, experience, training, or education" to testify as an expert. *Id.*; *Saginaw Chippewa Indian Tribe v. Blue Cross Blue Shield of Mich.*, 745 F. Supp.

[3] Staples does not identify or define "SAMSHA." The court takes judicial notice that the term refers to the Substance Abuse and Mental Health Services Administration, a branch of the U.S. Department of Health and Human Services. *See* https://www.samhsa.gov/about (last accessed Sept. 26, 2025).

3d 524, 530 (E.D. Mich. 2024). In addition, to be admissible, the proffered testimony must be both relevant and reliable. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008).

Aside from Rule 702, the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), provided a non-exhaustive list of factors for courts to consult in evaluating the reliability of expert testimony, including "testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community." *United States v. Langan*, 263 F.3d 613, 621 (6th Cir. 2001) (citing *Daubert*, 509 U.S. at 593–94). However, the reliability test is "'flexible,' and the *Daubert* factors do not constitute a 'definitive checklist or test,' but may be tailored to the facts of a particular case." *In re Scrap Metal Litig.*, 527 F.3d at 529 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999). The Sixth Circuit has "recognized that the *Daubert* factors 'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the reliability of expert testimony.'" *Id.* (quoting *Gross v. Comm'r*, 272 F.3d 333, 339 (6th Cir. 2001)).

The standard to exclude an expert's testimony under *Daubert* is high, and "rejection of expert testimony is the exception, rather than the rule." *Nusbaum v. Enlighten Fam. Chiropractic, LLC*, No. 19-cv-10223, 2023 WL 319782, at *5 (E.D. Mich. Jan. 19, 2023) (collecting cases). Typically, "[i]f there is a reasonable factual basis for expert testimony, it should be admitted." *Id.* (citations omitted). Moreover, the Sixth Circuit has emphasized the distinction between the "credibility and accuracy" of a proffered opinion and its reliability. *In re Scrap Metal*, 527 F.3d at 529. "The task for the district court in deciding whether an expert's opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation." *Id.* at 529–30. Generally, any issue regarding the

credibility or accuracy of admitted expert testimony goes to the weight rather than the admissibility of the evidence, and it can be addressed via cross-examination and the "presentation of contrary evidence" by opposing counsel. *Id.* at 530 (quoting *Daubert*, 509 U.S. at 596).

III. THE PARTIES' ARGUMENTS

With respect to each of the four areas addressed by Staples' Report, the government argues that Staples is not a medical professional, does not purport to be a medical professional, and should not be permitted to offer medical opinions based on medical sources about (1) the applicable standard of care in rural settings, (2) whether Marks' practice demonstrated characteristics of a "pill mill"; (3) the treatment of patients with both substance use disorder and chronic pain and the proper interpretation of an HHS report and a CDC image documenting the "chronic pain experience"; or (4) the proper use of urine drug testing in the treatment of chronic pain patients.

Second, the government argues that Staples does not state an opinion "applying any of his purported experience or sources to the facts of this case" in two of the areas addressed in his report. (Doc. No. 308 at 9.) "Specifically," the government points out, "areas (3) (patient stigma) and (4) (urine drug testing) contain no opinions about Marks or this case." (*Id.*) In a footnote, the government also points out that, in the section on rural healthcare, Staples states that he "conducted an investigation into the nearest pain management facilities in the area" near Marks' practice, but he neglects to relay what his investigation revealed. (*Id.* at 9 n.3 (citing Doc. No. 287-1 at 8).) The government argues that, having omitted this information from his report, Staples should not be permitted to offer the results of that purported investigation at trial.

Third, the government argues that none of Staples' proposed testimony is relevant to any issue in this case and, in particular, that the court has already held that Marks is prohibited from offering evidence on the characteristics of a pill mill (*see* Transcript, Doc. No. 167 at 40 (oral ruling on Motions in Limine)) and, therefore, that she should not be able to introduce this evidence

through Staples. The government acknowledges that the topic of urine drug testing is generally relevant in this case but that Staples does not offer any actual *opinions* on this topic that relate to the facts of this case. Finally, the government argues that, insofar as Staples' proposed testimony bears any relevance to the issues in this case, it is cumulative of the evidence that the defendants' medical experts intend to offer.

In response, Marks acknowledges that only medical experts can offer medical opinions, but she contends that the government is simply mistaken in arguing that Staples intends to testify as a medical expert. Instead, she argues, he has expertise in criminal investigations on matters involving healthcare and controlled substances. She explains that his testimony "will be used much like the Government uses a law enforcement expert in a 21 U.S.C. § 841(a) case to interpret drug distribution code language" or, more specifically, "like the Government uses a diversion investigator in a 21 U.S.C. § 841(b) case to explain what red flags of diversion a prescriber ignored prior to issuing a particular prescription." (Doc. No. 358 at 5 (footnote omitted).) She seeks to offer Staples' testimony to "rebut the government's circumstantial evidence of diversion and noncompliance." (*Id.* at 6.) She maintains that it would be "fundamentally unfair to allow the Government to present evidence of diversion and red flags without allowing the defense to rebut the prejudicial effect of that admission." (*Id.* at 7.)

Regarding the relevance of Staples' testimony, Marks offers a confusing discussion of how the government is purportedly conflating the term "standard of care" with the term "practice of medicine." (*Id.* at 8.) She argues, essentially, that, while those terms are different, "standard of care" simply means "compliance," which she defines as "the legal measure for determining if what [a medical professional] did was adequate." (*Id.*) She then describes Staples' expert disclosure as

> notif[ying] the Government that Mr. Staples will testify to the complexity of physician documentation and compliance requirements and describe their strain on practicing physicians. . . . In describing these complexities in documentation and compliance, the disclosure alerts the Government that, Staples will provide an opinion that many drug-seeking patients utilize deceit to obtain drugs, which is nearly impossible for physicians to detect. . . . Staples then explains he will testify to the lack of access to care that many rural patients, including Marks' patients[,] suffer from. This sentence is then followed by another, notifying the Government exactly how Staples plans to explain the impact of this lack of access on Marks, as well as rural physicians more broadly (*i.e.*, it impacts medical decision making, etc.). . . . Instead of expert information showing activities that are consistent with distribution [as government witnesses are often permitted to do], Staples will provide the jury with information that shows the complexity of medical care, access to medical care, treating patients, and compliance intricacies which will aid the jury in making the decision whether Marks was consistent with rendering medical care or distribution [of drugs].

(*Id.* at 9–10.)

Finally, Marks refutes the suggestion that Staples' proposed testimony would be cumulative of her other expert witnesses' testimony as based on the incorrect assumption that Staples intends to offer medical opinions. Marks again disclaims any intention to offer medical opinion testimony through Staples and characterizes his proposed opinions as concerning "the unique circumstances that physicians in rural areas face and how this adversely affects their practice." (*Id.* at 11.) She specifically denies that Staples' proposed testimony on the "red flags" characteristic of a "pill mill" is a medical opinion and characterizes it instead as "the very criteria undercover pill mill fake patients try and elude unsuspecting doctors with in every one of these diversion investigations." (*Id.*) She maintains that Staples should be permitted to offer his opinion that none of the "red flags" typically identified by law enforcement as associated with pill mills are associated with Marks' practice. (*Id.*)

The government filed a Reply in further support of its motion. (Doc. No. 372.) Here, the government characterizes the defendant's Response as "clarif[ying]" that Staples' actual intended

testimony would deviate substantially from his Report and, moreover, "would be about impermissible or non-expert topics," specifically,

> (1) Telling the jury that there is a lower standard of care for a medical professional to meet than that required by law;
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> (2) Describing drug diversion and compliance measures; and
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> (3) Telling the jury that the Government did a bad diversion investigation and that Marks did not operate a pill mill.

(Doc. No. 372 at 1–2.) Regarding these three topics, the government asserts that (1) the first is inconsistent with the Supreme Court's opinion in *Ruan v. United States*, 597 U.S. 450 (2022), and simply an incorrect statement of the law, insofar as Staples appears to be opining that, if Marks satisfied the "standard of care" applicable to rural healthcare practitioners, then she cannot be guilty; (2) Staples might be permitted to testify as a lay witness "as to basic drug diversion and compliance issues, but that is not what Staples' expert disclosure proposes" (*id.* at 3);[4] and (3) testimony on the "credibility" of the government's investigation or that Marks' practice was not a pill mill violates the court's previous order (*id.* at 5).

IV. DISCUSSION

The court finds that Marks' Response to the Motion to Exclude largely serves to muddy the issues. In particular, in explaining Staples' proposed opinions, the Response deviates substantially from the Report itself, which does not actually offer any opinion regarding "the complexity of physician documentation and compliance requirements"; nor does it "describe their

[4] The government states that, for example, it will likely present non-expert testimony from a DEA agent "regarding drug diversion issues, including testimony based on knowledge and observations from law enforcement's investigations into drug diversion in Tennessee, and the types of opioids sold on the street there (including the popularity of the exact dosages that Marks . . . defaulted to giving to every patient)." (Doc. No. 372 at 4.) However, the government states, it "does not intend to ask a lay diversion witness 'what red flags of diversion a prescriber ignored prior to issuing a particular prescription[],'" because "those are medical opinions." (*Id.*)

strain on practicing physicians" or provide notice that Staples intends to offer an opinion that "many drug-seeking patients utilize deceit to obtain drugs, which is nearly impossible for physicians to detect." (*See* Doc. No. 359 at 9–10.) To be clear, Staples will not be permitted to offer expert opinions that are outside the scope of his Report. Aside from that conclusion, the court addresses, below, the actual areas of testimony identified in Staples' Report.[5]

A. "The Challenges of 'Rural Healthcare'"

Regarding his first proposed topic, the government argues that Staples is not a medical practitioner of any kind and therefore is not qualified to offer medical opinions, using medical jargon, about the appropriate standard of medical care in any setting. More specifically, the government asserts that Staples is not qualified to opine that the applicable standard of care that applies to medical practitioners in the rural setting is different from that governing medical practitioners in urban settings.

The court agrees that Staples cannot offer medical testimony or testify about the medical standard of care *per se*. Consequently, he cannot offer an opinion that the practice of medicine in a rural setting changes the applicable standard of care—this is a medical issue. Nor may he opine that the rural setting somehow alters the legal requirements for proving a violation of § 841(a). However, insofar as Marks' defense in this case is that she subjectively believed that she was authorized to issue the prescriptions at issue, because she did so in the usual course of her professional practice and with a legitimate medical purpose, Staples' testimony about the unique challenges facing medical practitioners in rural areas appears to have some bearing on whether her belief was objectively reasonable.

[5] The government states that it "would not object to Staples providing non-expert testimony as to basic drug diversion and compliance issues." (Doc. No. 372 at 3.) The court expresses no opinion on this issue.

As such, the testimony appears to be relevant and admissible. The parties can hash out the issue of jury instructions later in this case, but the law is clear that, to obtain a conviction under § 841(a), the government must prove that the defendant "knew that he or she was acting in an unauthorized manner, or intended to do so," *Ruan*, 597 U.S. at 454. In other words, "the government [is] required to prove beyond a reasonable doubt that [Marks] knew [her] prescriptions were unauthorized—meaning that they lacked a 'legitimate medical purpose' and were outside 'the usual course of [her] professional practice.'" *United States v. Sadrinia*, 134 F.4th 887, 893 (6th Cir. 2025) (quoting *Ruan*, 597 U.S. at 454; 21 C.F.R. § 1306.04(a)). Under *Ruan*, "liability cannot turn on 'the mental state of a hypothetical "reasonable" doctor.'" *United States v. Campbell*, 135 F.4th 376, 386 (6th Cir. 2025) (quoting *Ruan*, 597 U.S. at 465). Instead, "the government must prove that the 'defendant himself' subjectively knew that his acts were without a legitimate medical purpose in the usual course of his professional practice." *Id.* (quoting *Ruan*, 597 U.S. at 465–67).

In light of this standard, the Sixth Circuit has clarified that objective *good faith* is not relevant in this context. *United States v. Anderson*, 67 F.4th 755, 765 (6th Cir. 2023). At the same time, it has long been recognized that the "objective unreasonableness of particular conduct will be evidence of the intent of the actor." *Smith v. Wade*, 461 U.S. 30, 64 n.4 (1983); *see also United States v. Kahn*, 58 F.4th 1308, 1316 n.4 (10th Cir. 2023) ("*Ruan* holds that an unreasonable pharmacist may not be convicted if he did not intend to act in an unauthorized way. Of course, evidence of objective unreasonableness may support a jury's ultimate finding that a defendant subjectively intended to act without authorization."); *United States v. Iwas*, No. 18-20769, 2023 WL 6702114, at *1 (E.D. Mich. Oct. 12, 2023) ("As the government puts it, '[t]he more outside the usual course of professional practice, the stronger the inference the defendant acted knowingly

and intentionally.'"). Because objective *unreasonableness* is admissible circumstantial evidence of an actor's intent, objective *reasonableness* of a defendant's conduct may also inform a jury's assessment of the defendant's subjective intent. Staples' proposed testimony about the unique challenges posed by the rural setting in which Marks' practice was situated may be relevant to the objective reasonableness of her prescribing practices.

To be sure, Staples may not offer a medical opinion, but his experience and training as a healthcare regulatory consultant, investigator, and expert provide him a sufficient basis to proffer an opinion that the rural setting of Marks' practice posed significant challenges for providers not found in urban settings. The Motion to Exclude is, therefore, **GRANTED** with respect to Staples' proposed testimony about the standard of care, but **DENIED** as to his proposed testimony about the unique challenges confronting healthcare practitioners in rural communities. (*See* Doc. No. 358 at 11 ("[T]he [Report] states that Staples will testify on the unique circumstances that physicians in rural areas face and how this adversely affects their practice.").)

B. "Characteristics of a 'Pill Mill' and 'Bad Faith controlled substance prescribing'"[6]

Before a previous setting of the trial in this case, the parties filed, and the court ruled on, numerous motions in limine, including the government's motion to exclude testimony from the defendants regarding "whether other physicians, medical professionals, or any other individuals were or were not charged." (Doc. No. 120 at 7.) In responding to this motion, the defendants[7] agreed that they did not intend to elicit testimony about "a charging decision in another case."

[6] Marks' Response to the Motion to Exclude does not specifically address the issue of "bad faith prescribing," and Staples' Report basically just defines a "pill mill" as an "example of 'bad faith' prescribing." (Doc. No. 287-1 at 8.) The court, therefore, does not consider these to be separate issues.

[7] At that point, Marks' co-defendant Mehta had not yet pleaded guilty and been severed from this case.

(Doc. No. 146 at 12.) However, they also argued that they "should not be foreclosed from asking agents about the hallmarks of a 'pill mill' case or the wide swath of conduct that is captured by this particular charging statute." (*Id.*) The court addressed this issue orally at a pretrial conference on August 25, 2021, stating that, insofar as the defendants wanted to question law enforcement agents about the "hallmarks of a pill mill case," such testimony "would not be allowed," as it "gets into the charging decision by the government, which is really no concern of the jury." (Transcript, Doc. No. 167 at 40.)

Here, Staples seeks to testify both about the hallmarks of a pill mill and that Marks' practice did not demonstrate any of the characteristics of a pill mill. The government argues that the first part of the proposed testimony is barred by the court's previous ruling, that the second part constitutes medical opinion testimony, and that both are irrelevant because the government does not intend to argue that Marks' medical practice was a pill mill. Marks responds that the testimony is not medical evidence, but she does not address the government's other arguments.

Staples will not be permitted to argue about the hallmarks or characteristics of a pill mill or that Marks' practice did not carry any of these hallmarks. As the court already held, this evidence implicates the government's charging decision. In addition, it simply is not relevant, because the government does not take the position that Marks and her former co-defendant were operating a so-called pill mill. The government's Motion to Exclude will be **GRANTED** in this respect.

C. Patient "Stigma"

Marks does not address the issue of "patient stigma" in responding to the government's Motion to Exclude. The court finds that this part of Staples' opinion does not offer an opinion tied to or related to any evidence or issue in this case, appears to constitute medical opinion, and is

simply not relevant. The motion will be **GRANTED** with respect to this part of Staples' proffered evidence.

D. Urine Drug Testing

Regarding Staples' opinions about the use of urine drug testing as a "tool" to be utilized by medical practitioners but not the "sole basis for diagnosis and treatment decisions" and his long list of factors that may cause a negative drug urine test, the court finds that this testimony steps over the line between lay and medical opinion and is not admissible through Staples. In any event, Marks does not address the government's argument regarding this portion of Staples' Report or attempt to justify its introduction. The government's motion will be **GRANTED** with respect to Staples' proffered opinions about urine drug testing.

V. CONCLUSION AND ORDER

For the reasons set forth herein, the government's Motion to Exclude (Doc. No. 308) is **GRANTED IN PART AND DENIED IN PART**. The motion is **DENIED**, insofar as Staples will be allowed to offer limited expert testimony on the "unique circumstances that physicians in rural areas face and how this adversely affects their practice" (*see* Doc. No. 358 at 11), but he may not offer a medical opinion while doing so. In all other respects, the motion is **GRANTED**, and Staples may not opine about the red flags typically associated with a pill mill or whether Marks' practice exhibited any of these markers, patient stigma, or the appropriate use of urine testing by pain medicine practitioners.

It is so **ORDERED**.

ALETA A. TRAUGER
United States District Judge